

K093849

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1. Submitter's Information: 21 CFR 807.92(a)(1)

MEDISON CO., LTD.
1003, Daechi-dong, Gangnam-gu,
Seoul 135-280, Korea

Contact Person:
Mr. Kyung-Am, Shim
Regulatory Affairs Manager

Telephone: 82.2.2194.1381
Facsimile: 82.2.2194.1399
Email: kashim@medison.com

Data Prepared: September 7, 2009

2. Name of the device:Common/Usual Name:

Diagnostic Ultrasound System and Accessories

Proprietary Name:

ACCUVIX V10 Diagnostic Ultrasound System

| <u>Classification Names:</u> | <u>FR Number</u> | <u>Product Code</u> |
|--|------------------|---------------------|
| Ultrasonic Pulsed Doppler Imaging System | 892.1550 | IYN |
| Ultrasound Pulsed Echo Imaging System | 892.1560 | IYO |
| Diagnostic Ultrasound Transducer | 892.1570 | ITX |

3. Identification of the predicate or legally marketed device:

K070813, ACCUVIX V10 Diagnostic Ultrasound System
K092159, ACCUVIX V20 Diagnostic Ultrasound System

4. Device Description:

The ACCUVIX V10 is a general purpose, mobile, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as 2D mode, M mode, Color Doppler mode, Power Doppler mode, PW Spectral Doppler, CW Spectral Doppler mode, and Tissue Doppler Image mode on the LCD display. It also provides the 3D/4D imaging mode using the 3D/4D probe in the Mechanical scan mode.

The ACCUVIX V10 has real time acoustic output display with two basic indices, a

mechanical index and a thermal index, which are both automatically displayed. The system also provides for the measurement of anatomical structures and for analysis packages that provide information used for clinical diagnostic purposes by competent health care professionals.

The ACCUVIX V10 has been designed to meet the following product safety standards:

- UL 60601-1, Safety requirements for Medical Equipment
- CSA C22.2 No. 601.1, Safety requirements for Medical Equipment
- IEC60601-2-37, Diagnostic Ultrasound Safety Standards
- EN/IEC60601-1, Safety requirements for Medical Equipment
- EN/IEC60601-1-2, EMC requirements for Medical Equipment
- NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- IEC 61157, Declaration of the acoustic output
- ISO10993-1, Biocompatibility

5. Intended Uses:

The ACCUVIX V10 system and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

The clinical applications include:

General, abdomen, obstetrics, gynecology, vascular, extremity, pediatric, cardiac, breast, urology, neonatal cephalic, trans-esophageal, intraoperative and etc.

6. Technological Characteristics:

The ACCUVIX V10 is substantially equivalent to the ACCUVIX V10 Diagnostic Ultrasound System, cleared via K070813, and the ACCUVIX V20 Diagnostic Ultrasound System, cleared via K092159. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All system allow for specialized measurements of structures and flow, and calculations.

END of 510(K) Summary



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JAN 19 2010

Medison Co., Ltd.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K093849

Trade/Device Name: ACCUVIX V10 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: January 7, 2010
Received: January 8, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the ACCUVIX V10 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

| | | |
|----------------|-------------------|-------------------|
| <u>3D2-6ET</u> | <u>C2-61C</u> | <u>NER4-9ES</u> |
| <u>3D4-8ET</u> | <u>C3-71M</u> | <u>NEV4-9ES</u> |
| <u>3D4-9ES</u> | <u>C4-9/10ED</u> | <u>L4-7EL</u> |
| <u>3D5-9EK</u> | <u>EC4-9IS</u> | <u>L5-12/50EP</u> |
| <u>V6-12</u> | <u>ER4-9/10ED</u> | <u>L5-13IS</u> |
| <u>C2-5EL</u> | <u>EV4-9/10ED</u> | <u>L6-12IS</u> |

| | | |
|----------------|---------------|---------------|
| <u>L7-16IS</u> | <u>MPT4-7</u> | <u>P3-8CA</u> |
| <u>L8-15IS</u> | <u>P2-4AC</u> | <u>CW 2.0</u> |
| <u>LS5-13</u> | <u>P2-4BA</u> | <u>CW 4.0</u> |
| <u>LT4-7</u> | <u>P3-5AC</u> | |

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

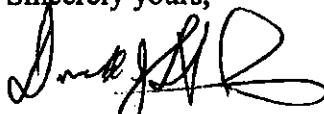
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Andrew Kang at (301) 796-6544.

Sincerely yours,



Donald J. St. Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: K093849

Device Name: CW 4.0 for use with ACCUVIX V10

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative (See Note 6) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | P | | |
| | Small Organ (See Note 5) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | P | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| | Musculo-skel. (Convent.) | | | | | | | |
| | Musculo-skel. (Superfic.) | | | | | | | |
| Cardiac | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| | Cardiac Adult | | | | P | | | |
| | Cardiac Pediatric | | | | P | | | |
| Peripheral Vessel | Trans-esophageal (Cardiac) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | P | | | |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K070813; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult; pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE) (OIVD)
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number K093849

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: K093849

Device Name: CW 2.0 for use with ACCUVIX V10

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative (See Note 6) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (See Note 5) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | P | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| | Musculo-skel. (Convent.) | | | | | | | |
| Cardiac | Musculo-skel. (Superfic.) | | | | | | | |
| | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| | Cardiac Adult | | | | P | | | |
| Peripheral Vessel | Cardiac Pediatric | | | | P | | | |
| | Trans-esophageal (Cardiac) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | P | | | |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K070813; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, CDER (CDER) (OIVD)
RVO
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number K093849

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: *K093849*

Device Name: P3-8CA for use with ACCUVIX V10

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | | | | | | | |
| | Abdominal | P | P | P | P | P | Note 1 | Note 4, 7 |
| | Intra-operative (See Note 6) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (See Note 5) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | P | P | P | P | P | Note 1 | Note 4, 7 |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| | Musculo-skel. (Convent.) | | | | | | | |
| | Musculo-skel. (Superfic.) | | | | | | | |
| Cardiac | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| | Cardiac Adult | P | P | P | P | P | Note 1 | Note 4, 7 |
| | Cardiac Pediatric | P | P | P | P | P | Note 1 | Note 4, 7 |
| Peripheral Vessel | Trans-esophageal (Cardiac) | | | | | | | |
| | Other (spec.) | | | | | | | |
| | Peripheral vessel | | | | | | | |
| Other (spec.) | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K092159; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ (O'DVD)
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number *K093849*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: 1093849

Device Name: P3-5AC for use with ACCUVIX V10

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | | | | | | | |
| | Abdominal | P | P | P | P | P | Note 1 | Note 4, 7 |
| | Intra-operative (See Note 6) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (See Note 5) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | P | P | P | P | P | Note 1 | Note 4, 7 |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| | Musculo-skel. (Convent.) | | | | | | | |
| | Musculo-skel. (Superfic.) | | | | | | | |
| Cardiac | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| | Cardiac Adult | P | P | P | P | P | Note 1 | Note 4, 7 |
| | Cardiac Pediatric | P | P | P | P | P | Note 1 | Note 4, 7 |
| Peripheral Vessel | Trans-esophageal (Cardiac) | | | | | | | |
| | Other (spec.) | | | | | | | |
| | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K070813; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ (OIVD)
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number 1093849

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: K093849

Device Name: P2-4BA for use with ACCUVIX V10

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | | | | | | | |
| | Abdominal | P | P | P | P | P | Note 1 | Note 4, 7 |
| | Intra-operative (See Note 6) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (See Note 5) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | P | P | P | P | P | Note 1 | Note 4, 7 |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| | Musculo-skel. (Convent.) | | | | | | | |
| | Musculo-skel. (Superfic.) | | | | | | | |
| Cardiac | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| | Cardiac Adult | P | P | P | P | P | Note 1 | Note 4, 7 |
| | Cardiac Pediatric | P | P | P | P | P | Note 1 | Note 4, 7 |
| Peripheral Vessel | Trans-esophageal (Cardiac) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K092159; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE) (OIVD)
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number K093849

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: **K093849**

Device Name: P2-4AC for use with ACCUVIX V10

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | | | | | | | |
| | Abdominal | P | P | P | P | P | Note 1 | Note 4, 7 |
| | Intra-operative (See Note 6) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (See Note 5) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | P | P | P | P | P | Note 1 | Note 4, 7 |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| | Musculo-skel. (Convent.) | | | | | | | |
| | Musculo-skel. (Superfic.) | | | | | | | |
| Cardiac | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| | Cardiac Adult | P | P | P | P | P | Note 1 | Note 4, 7 |
| | Cardiac Pediatric | P | P | P | P | P | Note 1 | Note 4, 7 |
| Peripheral Vessel | Trans-esophageal (Cardiac) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K070813; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE) (ODVD)
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number **K093849**

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: K093849

Device Name: MPT4-7 for use with ACCUVIX V10

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative (See Note 6) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (See Note 5) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | P | P | P | | P | Note 1 | Note 7, 8 |
| | Musculo-skel. (Convent.) | | | | | | | |
| Cardiac | Musculo-skel. (Superfic.) | | | | | | | |
| | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| | Cardiac Adult | | | | | | | |
| Peripheral Vessel | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (Cardiac) | N | N | N | | N | Note 1 | Note 7, 8 |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N=new indication; P=previously cleared under K092159; E=added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE), (OIVD)
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number K093849

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: *K093849*

Device Name: LT4-7 for use with ACCUVIX V10

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative (See Note 6) | N | N | N | | N | Note I | Note 8, 9 |
| | Intra-operative (Neuro.) | N | N | N | | N | Note I | Note 8, 9 |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (See Note 5) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| Cardiac | Musculo-skel. (Convent.) | | | | | | | |
| | Musculo-skel. (Superfic.) | | | | | | | |
| | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number *K093849*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: **K093849**

Device Name: LS5-13 for use with ACCUVIX V10

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative (See Note 6) | P | P | P | | P | Note 1 | Note 8, 9 |
| | Intra-operative (Neuro.) | P | P | P | | P | Note 1 | Note 8, 9 |
| | Laparoscopic | | | | | | | |
| | Pediatric | P | P | P | | P | Note 1 | Note 8, 9 |
| | Small Organ (See Note 5) | P | P | P | | P | Note 1 | Note 8, 9 |
| | Neonatal Cephalic | P | P | P | | P | Note 1 | Note 8, 9 |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| | Musculo-skel. (Convent.) | P | P | P | | P | Note 1 | Note 8, 9 |
| | Musculo-skel. (Superfic.) | P | P | P | | P | Note 1 | Note 8, 9 |
| Cardiac | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (Cardiac) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | P | P | P | | P | Note 1 | Note 5, 6, 9 |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K060087; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ (ODVD)
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number **K093849**

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: *K093849*

Device Name: L8-15IS for use with ACCUVIX V10

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative (See Note 6) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | P | P | P | | P | Note 1 | Note 2, 5, 6, 9 |
| | Small Organ (See Note 5) | P | P | P | | P | Note 1 | Note 2, 5, 6, 9 |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| | Musculo-skel. (Convent.) | P | P | P | | P | Note 1 | Note 2, 5, 6, 9 |
| | Musculo-skel. (Superfic.) | P | P | P | | P | Note 1 | Note 2, 5, 6, 9 |
| Cardiac | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (Cardiac) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral vessel | Peripheral vessel | P | P | P | | P | Note 1 | Note 2, 5, 6, 9 |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K070813; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE) (OVID)
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number *K093849*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: *K093849*

Device Name: L7-16IS for use with ACCUVIX V10

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative (See Note 6) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | P | P | P | | P | Note 1 | Note 2, 5, 6, 9 |
| | Small Organ (See Note 5) | P | P | P | | P | Note 1 | Note 2, 5, 6, 9 |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| | Musculo-skel. (Convent.) | P | P | P | | P | Note 1 | Note 2, 5, 6, 9 |
| | Musculo-skel. (Superfic.) | P | P | P | | P | Note 1 | Note 2, 5, 6, 9 |
| Cardiac | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| Peripheral Vessel | Trans-esophageal (Cardiac) | | | | | | | |
| | Other (spec.) | | | | | | | |
| | Peripheral vessel | P | P | P | | P | Note 1 | Note 2, 5, 6, 9 |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K092159; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ (ODE) (CDER)
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number *K093849*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: K093849

Device Name: L6-12IS for use with ACCUVIX V10

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|--------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative (See Note 6) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | P | P | P | | P | Note 1 | Note 2, 5, 6, 7, 9 |
| | Small Organ (See Note 5) | P | P | P | | P | Note 1 | Note 2, 5, 6, 7, 9 |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| | Musculo-skel. (Convent.) | P | P | P | | P | Note 1 | Note 2, 5, 6, 7, 9 |
| | Musculo-skel. (Superfic.) | P | P | P | | P | Note 1 | Note 2, 5, 6, 7, 9 |
| Cardiac | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | P | P | P | | P | Note 1 | Note 2, 5, 6, 7, 9 |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K070813; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~, (ODVD)
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number K093849

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: K 093849

Device Name: L5-13IS for use with ACCUVIX V10

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|--------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative (See Note 6) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | P | P | P | | P | Note 1 | Note 2, 5, 6, 7, 9 |
| | Small Organ (See Note 5) | P | P | P | | P | Note 1 | Note 2, 5, 6, 7, 9 |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| | Musculo-skel. (Convent.) | P | P | P | | P | Note 1 | Note 2, 5, 6, 7, 9 |
| | Musculo-skel. (Superfic.) | P | P | P | | P | Note 1 | Note 2, 5, 6, 7, 9 |
| Cardiac | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| Peripheral Vessel | Trans-esophageal (Cardiac) | | | | | | | |
| | Other (spec.) | | | | | | | |
| | Peripheral vessel | P | P | P | | P | Note 1 | Note 2, 5, 6, 7, 9 |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K092159; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ (OIVD)
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number K 093849

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: *K093849*

Device Name: L5-12/50EP for use with ACCUVIX V10

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|--------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative (See Note 6) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | P | P | P | | P | Note 1 | Note 2, 5, 6, 7, 9 |
| | Small Organ (See Note 5) | P | P | P | | P | Note 1 | Note 2, 5, 6, 7, 9 |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| | Musculo-skel. (Convent.) | P | P | P | | P | Note 1 | Note 2, 5, 6, 7, 9 |
| | Musculo-skel. (Superfic.) | P | P | P | | P | Note 1 | Note 2, 5, 6, 7, 9 |
| Cardiac | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | P | P | P | | P | Note 1 | Note 2, 5, 6, 7, 9 |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K070813; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE) (OIVD)
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number *14093849*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: 1K093849

Device Name: L4-7EL for use with ACCUVIX V10

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative (See Note 6) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | P | P | P | | P | Note 1 | Note 2, 5, 6, 9 |
| | Small Organ (See Note 5) | P | P | P | | P | Note 1 | Note 2, 5, 6, 9 |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| | Musculo-skel. (Convent.) | P | P | P | | P | Note 1 | Note 2, 5, 6, 9 |
| | Musculo-skel. (Superfic.) | P | P | P | | P | Note 1 | Note 2, 5, 6, 9 |
| | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (Cardiac) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | P | P | P | | P | Note 1 | Note 5, 6, 9 |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K092159; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

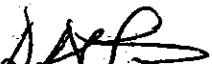
Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ (OIVD)
 Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)

Division of Radiological Devices

510(k) Number 1K093849

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

K093849

Device Name:

NEV4-9ES for use with ACCUVIX V10

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative (See Note 6) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (See Note 5) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | P | P | P | | P | Note 1 | Note 2, 7, 8 |
| | Trans-vaginal | P | P | P | | P | Note 1 | Note 2, 7, 8 |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| | Musculo-skel. (Convent.) | | | | | | | |
| | Musculo-skel. (Superfic.) | | | | | | | |
| | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (Cardiac) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K070813; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE) (OIVD)
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number K093849

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: K093849

Device Name: NER4-9ES for use with ACCUVIX V10

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative (See Note 6) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (See Note 5) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | P | P | P | | P | Note 1 | Note 2, 7, 8 |
| | Trans-vaginal | P | P | P | | P | Note 1 | Note 2, 7, 8 |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| | Musculo-skel. (Convent.) | | | | | | | |
| | Musculo-skel. (Superfic.) | | | | | | | |
| | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (Cardiac) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K070813; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE) (O'DVD)
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number K093849

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: **K093849**
 Device Name: **EV4-9/10ED for use with ACCUVIX V10**
 Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative (See Note 6) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (See Note 5) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | P | P | P | | P | Note 1 | Note 2, 7, 8 |
| | Trans-vaginal | P | P | P | | P | Note 1 | Note 2, 7, 8 |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| | Musculo-skel. (Convent.) | | | | | | | |
| | Musculo-skel. (Superfic.) | | | | | | | |
| | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (Cardiac) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K092159; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

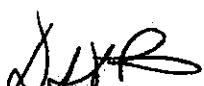
Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ (OIVD)
 Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)

Division of Radiological Devices

510(k) Number K093849

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

K093849

Device Name: ER4-9/10ED for use with ACCUVIX V10

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative (See Note 6) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (See Note 5) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | P | P | P | | P | Note 1 | Note 2, 7, 8 |
| | Trans-vaginal | P | P | P | | P | Note 1 | Note 2, 7, 8 |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| Cardiac | Musculo-skel. (Convent.) | | | | | | | |
| | Musculo-skel. (Superfic.) | | | | | | | |
| | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (Cardiac) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K092159; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ (O'DEV)
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number K093849

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: K093849

Device Name: EC4-9IS for use with ACCUVIX V10

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative (See Note 6) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (See Note 5) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | P | P | P | | P | Note 1 | Note 2, 7, 8 |
| Cardiac | Trans-vaginal | P | P | P | | P | Note 1 | Note 2, 7, 8 |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| | Musculo-skel. (Convent.) | | | | | | | |
| Peripheral Vessel | Musculo-skel. (Superfic.) | | | | | | | |
| | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K070813; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ (OIVD)
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number K093849

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: K093849

Device Name: C4-9/10ED for use with ACCUVIX V10

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | P | P | P | | P | Note 1 | Notes 2, 7, 8 |
| | Abdominal | P | P | P | | P | Note 1 | Notes 2, 7, 8 |
| | Intra-operative (See Note 6) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | P | P | P | | P | Note 1 | Notes 2, 7, 8 |
| | Small Organ (See Note 5) | P | P | P | | P | Note 1 | Notes 2, 7, 8 |
| | Neonatal Cephalic | P | P | P | | P | Note 1 | Notes 2, 7, 8 |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| | Musculo-skel. (Convent.) | | | | | | | |
| | Musculo-skel. (Superfic.) | | | | | | | |
| Cardiac | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| Peripheral Vessel | Trans-esophageal (Cardiac) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | P | P | P | | P | Note 1 | Notes 2, 7, 8 |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K070813; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Devices and Radiological Health (CDRH)
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number K093849

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: **K093849**Device Name: **C3-7IM for use with ACCUVIX V10**Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | P | P | P | | P | Note 1 | Notes 2, 7, 8 |
| | Abdominal | P | P | P | | P | Note 1 | Notes 2, 7, 8 |
| | Intra-operative (See Note 6) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | P | P | P | | P | Note 1 | Notes 2, 7, 8 |
| | Small Organ (See Note 5) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| | Musculo-skel. (Convent.) | | | | | | | |
| | Musculo-skel. (Superfic.) | | | | | | | |
| Cardiac | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (Cardiac) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K070813; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE), (OIVD)
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number K093849

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: **K093849**

Device Name: C2-6IC for use with ACCUVIX V10

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | P | P | P | | P | Note 1 | Notes 2, 7, 8 |
| | Abdominal | P | P | P | | P | Note 1 | Notes 2, 7, 8 |
| | Intra-operative (See Note 6) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | P | P | P | | P | Note 1 | Notes 2, 7, 8 |
| | Small Organ (See Note 5) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| Cardiac | Musculo-skel. (Convent.) | | | | | | | |
| | Musculo-skel. (Superfic.) | | | | | | | |
| | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (Cardiac) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K070813; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

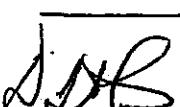
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging


 Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~, (OIVD)
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number K093849

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: **K093849**Device Name: **C2-5EL for use with ACCUVIX V10**Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | P | P | P | | P | Note 1 | Notes 2, 7, 8 |
| | Abdominal | P | P | P | | P | Note 1 | Notes 2, 7, 8 |
| | Intra-operative (See Note 6) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | P | P | P | | P | Note 1 | Notes 2, 7, 8 |
| | Small Organ (See Note 5) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| Cardiac | Musculo-skel. (Convent.) | | | | | | | |
| | Musculo-skel. (Superfic.) | | | | | | | |
| | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K070813; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE) - (ODV)
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number K093849

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: K 093849

Device Name: V6-12 for use with ACCUVIX V10

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative (See Note 6) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | P | P | P | | P | Note 1 | Note 2, 5, 6, 9 |
| | Small Organ (See Note 5) | P | P | P | | P | Note 1 | Note 2, 5, 6, 9 |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| | Musculo-skel. (Convent.) | P | P | P | | P | Note 1 | Note 2, 5, 6, 9 |
| | Musculo-skel. (Superfic.) | P | P | P | | P | Note 1 | Note 2, 5, 6, 9 |
| Cardiac | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | P | P | P | | P | Note 1 | Note 5, 6, 9 |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K092159; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~, (OIVD)
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number K 093849

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: **K093849**Device Name: **3D5-9EK for use with ACCUVIX V10**Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative (See Note 6) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (See Note 5) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | P | P | P | | P | Note 1 | Notes 2, 7, 8 |
| | Trans-vaginal | P | P | P | | P | Note 1 | Notes 2, 7, 8 |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| Cardiac | Musculo-skel. (Convent.) | | | | | | | |
| | Musculo-skel. (Superfic.) | | | | | | | |
| | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K092159; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ (O'DE) (O'DE)
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number **K093849**

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

K093849

Device Name: 3D4-9ES for use with ACCUVIX V10

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative (See Note 6) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (See Note 5) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | P | P | P | | P | Note 1 | Notes 2, 7, 8 |
| | Trans-vaginal | P | P | P | | P | Note 1 | Notes 2, 7, 8 |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| | Musculo-skel. (Convent.) | | | | | | | |
| Cardiac | Musculo-skel. (Superfic.) | | | | | | | |
| | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| | Cardiac Adult | | | | | | | |
| Peripheral Vessel | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (Cardiac) | | | | | | | |
| | Other (spec.) | | | | | | | |
| | Peripheral vessel | | | | | | | |
| Other (spec.) | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K070813; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE) (OIVD)
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number K093849

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: K093849

Device Name: 3D4-8ET for use with ACCUVIX V10

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | P | P | P | | P | Note 1 | Notes 2, 7, 8 |
| | Abdominal | P | P | P | | P | Note 1 | Notes 2, 7, 8 |
| | Intra-operative (See Note 6) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | P | P | P | | P | Note 1 | Notes 2, 7, 8 |
| | Small Organ (See Note 5) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| Cardiac | Musculo-skel. (Convent.) | | | | | | | |
| | Musculo-skel. (Superfic.) | | | | | | | |
| | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K070813; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, ~~Office of Devices and Radiological Health (CDRH)~~ (OIVD)
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number K093849

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: **K 093849**

Device Name: 3D2-6ET for use with ACCUVIX V10

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | P | P | P | | P | Note 1 | Notes 2, 7, 8 |
| | Abdominal | P | P | P | | P | Note 1 | Notes 2, 7, 8 |
| | Intra-operative (See Note 6) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | P | P | P | | P | Note 1 | Notes 2, 7, 8 |
| | Small Organ (See Note 5) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | | | | | | | |
| | Musculo-skel. (Convent.) | | | | | | | |
| | Musculo-skel. (Superfic.) | | | | | | | |
| Cardiac | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| Peripheral Vessel | Trans-esophageal (Cardiac) | | | | | | | |
| | Other (spec.) | | | | | | | |
| | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K070813; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~, **CDER**
 Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number **K 093849**

Section 1.3 INDICATIONS FOR USE

DIAGNOSTIC ULTRASOUND INDICATIONS STATEMENT

510(k) No.: *K093849*

Device Name: ACCUVIX V10 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation (*includes simultaneous B-mode) | | | | | | |
|---------------------------|------------------------------|---|---|-----|-----|-------------------|----------------------|--------------------------|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal (See Note 3) | P | P | P | P | P | Note 1 | Notes 2, 7, 8 |
| | Abdominal | P | P | P | P | P | Note 1 | Notes 2, 7, 8 |
| | Intra-operative (See Note 6) | N | N | N | | N | Note 1 | Note 7, 8, 9 |
| | Intra-operative (Neuro.) | N | N | N | | N | Note 1 | Note 7, 8, 9 |
| | Laparoscopic | | | | | | | |
| | Pediatric | P | P | P | P | P | Note 1 | Note 2, 4, 5, 6, 7, 8, 9 |
| | Small Organ (See Note 5) | P | P | P | | P | Note 1 | Note 2, 5, 6, 7, 8, 9 |
| | Neonatal Cephalic | P | P | P | P | P | Note 1 | |
| | Adult Cephalic | P | P | P | P | P | Note 1 | Note 4, 7 |
| | Trans-rectal | P | P | P | | P | Note 1 | Note 2, 3, 7, 8 |
| | Trans-vaginal | P | P | P | | P | Note 1 | Note 2, 3, 7, 8 |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Cardiac) | N | N | N | N | N | Note 1 | Notes 7, 8 |
| | Musculo-skel. (Convent.) | P | P | P | | P | Note 1 | Note 2, 5, 6, 7, 8, 9 |
| | Musculo-skel. (Superfic.) | P | P | P | | P | Note 1 | Note 2, 5, 6, 7, 8, 9 |
| Cardiac | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Cardiac Adult. | P | P | P | P | P | Note 1 | Note 4, 7 |
| | Cardiac Pediatric | P | P | P | P | P | Note 1 | Note 4, 7 |
| | Trans-esophageal (Cardiac) | N | N | N | N | N | Note 1 | Notes 7, 8 |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | P | P | P | P | P | Note 1 | Note 5, 6, 7, 9 |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared under K070813; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/CWD, B/Color Doppler, B/PWD/Color Doppler, B/Color Doppler/M, B/Color Doppler/CWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

[Signature] Concurrence of CDRH, Office of Device Evaluation (ODE) (OVID)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

510(k) Number *K093849*